

PSJ18 WALGREENS Opp Exh 3



U. S. Department of Justice
Drug Enforcement Administration
431 Howard Street
Detroit, Michigan 48226
(313) 234-4000

www.dea.gov

MAY 17 2006

Mr. Todd Polarolo
Distribution Center Manager
Walgreen Company
28727 Oregon Road
Perrysburg, Ohio 43551

Dear Mr. Polarolo:

During the month of March 2006, Diversion Investigators (DI) Angela Francis and James Rafalski of the Drug Enforcement Administration (DEA) completed a regulatory investigation of your firm. This regulatory investigation revealed recordkeeping inadequacies and security deficiencies. The discrepancies noted are as follows:

- 1) The formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient. The system set its standard of deviation from a normal ordering pattern in groupings of 25 customers, based on the number of non-controlled and controlled substance prescriptions filled by each customer. The system in place determined the amount of daily prescriptions filled by each of its customers of both non-controlled and controlled substance prescriptions. This amount was utilized to place each customer in groupings each containing 25 customers. Of these 25 customer groupings, the firm calculated the average order per item of each controlled substance. The firm then took the average and multiplied that figure by three. This calculated figure was then used as the base to report suspicious orders above such figure.

Section 1301.74(b) of Title 21 of the Code of Federal Regulations (CFR) requires the registrant design and operate a system to disclose to the registrant, suspicious orders of controlled substances, and inform DEA of suspicious orders.

- 2) The firm utilized shipping containers through contract carriers that indicated the tote contents were controlled substances. The firm utilized a numbered tote tag that was red in color solely on totes containing controlled substances.

Section 1301.74(e) of Title 21 of the CFR requires the registrant is responsible to employ precautions, to guard against storage or in-transit losses. Such precautions include that shipping containers do not indicate that contents are controlled substances.

- 3) The firm failed to submit written notification to DEA for central recordkeeping. The original purchase records were not maintained at the registered location. The

purchasing of controlled substances is performed at Walgreen Company Corporate Headquarters in Deerfield, Illinois. Original purchase records are maintained at the Walgreen Company facility in Deerfield, Illinois.

Section 1304.04(a) of Title 21 of the CFR requires the registrant notify and submit, in written format, their intent for central recordkeeping to DEA.

- 4) The biennial inventory and the inventory produced for the accountability audit failed to indicate if it was taken at the opening or close of business.

Section 1304.11(a) of Title 21 of the CFR requires the registrant indicate on the required inventories if it was taken at the opening of business or close of business.

- 5) The firm inaccurately recorded a loss in transit as a distribution which resulted in an accountability error in the Hydrocodone, 10mg product audited.

Section 1304.21(d) of Title 21 of the CFR requires the registrant record the date of distribution on the date controlled substances are actually distributed.

- 6) The firm's maintenance of purchase records was inadequate. The primary purchase record provided to DIs Francis and Rafalski was Walgreen Company Report Number REPB309. The report was a computer printout listing receipts solely by specific item number. The report failed to contain numerous required items. The REPB309 failed to contain the name, address and registration number of the vendor where the controlled substances were acquired. Additionally, incorrect DEA registration numbers were recorded on the purchase record. The primary purchase record should record the receipt as indicated on original purchase records, which are maintained at the corporate facility in Deerfield, Illinois. Since the original purchase records are not maintained at the registered location, central recordkeeping should be considered.

Section 1304.22(b) of Title 21 of the CFR requires the registrant maintain records with specific information. The information must include name of substance, each finished form, number of units acquired, date of acquisition, name, address and registration number of the person from whom the units were acquired.

- 7) The firm failed to ascertain which List I chemicals were handled at the registered location. Walgreen Company was advised their List I chemical products should have been identified as "PSE List I." The firm failed to identify all List I chemical products as "PSE List I."

Section 1309.71(8) of Title 21 of the CFR states that, in evaluating the effectiveness of security controls and procedures, DEA shall consider the registrant maintain a system for monitoring the receipt, distribution and disposition of List I chemicals in its operations.

- 8) The firm does not have knowledge of thresholds for List I chemicals. The firm was unable to determine if a system was in place to establish if the thresholds had been met for a regulated transaction.

Section 1310.03(f) of Title 21 of the CFR states the listed chemicals for which thresholds have been established and the quantitative threshold utilized, to determine whether a receipt or sale is a regulated transaction.

- 9) The firm does not accurately identify all List I chemicals handled by their facility. This failure to maintain the identity of List I chemicals resulted in the firm's inability to maintain a system for suspicious ordering of List I chemicals.

Sections 1310.05(a)(1) and 1310.05(b) of Title 21 of the CFR states each regulated person shall report to DEA List I chemical transactions of extraordinary quantity, uncommon method of payment or delivery, or any other circumstances, that is indicative of possible List I chemical violations. It further states that the reports are to be made orally to the Drug Enforcement Administration and written reports of such transactions shall be filed within 15 days after the regulated person becomes aware of the transaction.

- 10) The firm did not record the milligram amount of the List I chemical products on any of the records reviewed by investigators.

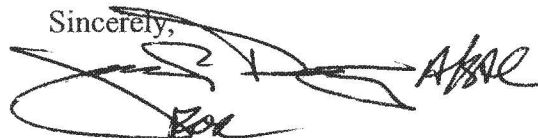
Section 1310.06(a)(3) of Title 21 of the CFR states that each required record shall include the quantity and form of packaging of the List I chemical.

This letter is formal notification that your failure to maintain adequate records and security for controlled substances and List I chemicals constitutes violations of the Controlled Substances Act. At this time, you are being afforded the opportunity to comply with the requirements of the Controlled Substances Act which were outlined by DIs Francis and Rafalski with the management of your firm in March, 2006.

Please advise this office in writing within thirty (30) days of the action taken or planned to correct these violations.

If you have any questions concerning this matter, please contact Acting Group Supervisor Barbara K. Dobric at 313-234-4000.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Corso', with a stylized flourish extending to the right.

Robert L. Corso
Special Agent in Charge
Detroit Field Division